IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

ABBVIE INC., et al.	§	**PLAINTIFFS**
	§	
	§	
v.	§	**Civil No. 1:24-cv-184-HSO-BWR**
	§	
	§	
LYNN FITCH	§	
in her official capacity as the Attorney General of the State of Mississippi	§	
	§	**DEFENDANT**

MEMORANDUM OPINION AND ORDER DENYING MOTION [8] FOR PRELIMINARY INJUNCTION

This matter comes before the Court on Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, and Allergan Sales, LLC's (collectively "Plaintiffs") Motion [8] for Preliminary Injunction. Having considered the allegations set forth in Plaintiffs' Complaint [1], the parties' Memoranda [9], [23], [25], and relevant legal authority, and having heard argument at a hearing held on July 12, 2024, the Court will deny the Motion [8].

I. BACKGROUND

Plaintiffs' Motion [8] asks the Court to enjoin the enforcement of Mississippi's recently enacted "Defending Affordable Prescription Drug Costs Act," 2024 Miss. H.B. 728 ("H.B. 728"), which took effect on July 1, 2024. House Bill 728 concerns a federal program referred to as Section 340B. *See* 42 U.S.C. § 256b. Under Section 340B, pharmaceutical manufacturers who participate in Medicaid and Medicare Part B must offer certain drugs at discounted prices to certain healthcare providers,

called "covered entities," that generally provide care for the poor. *See infra*, Part I.A. In essence, H.B. 728 requires manufacturers to deliver drugs ordered through the 340B Program to for-profit pharmacies called "contract pharmacies" with which covered entities have arrangements under which the pharmacy will dispense discounted 340B drugs to the covered entity's patients.

Plaintiffs assert that H.B. 728, in requiring them to deliver 340B drugs to an unlimited number of contract pharmacies, invalidly expands their obligation under federal law to provide discounted drugs to covered entities. *See* Mem. [9] at 13–16. They assert that H.B. 728 is preempted by § 256b, and that it constitutes a per se unconstitutional taking for private use under the Fifth Amendment to the United States Constitution. *See id.* at 13–22. Plaintiffs therefore seek a preliminary injunction to stay the enforcement of H.B. 728. *Id.* at 26. Because they are unable to satisfy the necessary elements for such relief, Plaintiffs' Motion [8] will be denied.

A. The Section 340B program

Section 340B requires pharmaceutical manufacturers that want the federal government to cover their drugs under Medicaid and Medicare Part B to provide discounts on their drugs to certain healthcare providers. 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5); *see Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). Those healthcare providers are "called '340B' or 'covered' entities," and "include public hospitals and community health centers, many of" which are "providers of safety-net services to the poor." *Astra USA, Inc. v.*

Santa Clara Cnty., 563 U.S. 110, 113 (2011); *see* Ex. [24-20] at 13–14 (outlining categories of covered entities). The 340B Program "is superintended by the Health Resources and Services Administration," ("HRSA"), "a unit of the Department of Health and Human Services," ("HHS"). *Astra*, 563 U.S. at 113.

"Drug manufacturers," such as Plaintiffs, "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" ("PPA") "used nationwide." *Id.* These agreements "are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Id.* PPAs must "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." § 256b(a)(1).

Through Section 340B, Congress leverages the federal government's subsidization of healthcare—Medicare and Medicaid cover "almost half the annual nationwide spending on prescription drugs," *Sanofi Aventis*, 58 F.4th at 699 (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022))—to aid covered entities in their mission to care for low-income Americans, *see id.* The statute enables covered entities "to give uninsured patients drugs at little or no cost." *Id.* Covered entities also obtain "extra revenue from serving insured patients" because "they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Id.* (citing Gov't Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program*

Offer Benefits, but Federal Oversight Needs Improvement 17–18 (GAO-11-836, Sept. 2011)).

As the Supreme Court recently observed, Congress arguably "intended for the 340B program's drug reimbursements to subsidize other services provided by 340B hospitals" because they "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 730, 738 (2022). A federal district court has also discussed how "the purpose of the 340B program was to provide a means to make 340B entities profitable." *Genesis Health Care, Inc. v. Becerra*, No. 4:19-CV-01531-RBH, 2023 WL 7549156, at *1 (D.S.C. Nov. 3, 2023).

According to a House Report on Section 340B, Congress enacted Section 340B in response to pharmaceutical manufacturers increasing prices of drugs to make up for lost revenue after Congress enacted the Omnibus Budget Reconciliation Act of 1990, which created the Medicaid Drug Rebate Program. *Id.* (citing H.R. Rep. No. 102-384(II), at 7–11 (1992)). Congress's goal, as stated in House Report 384(II), was to protect covered entities from such price increases because they "reduced the level of services and the number of individuals that these hospitals and clinics" could serve. *Id.* (quoting H.R. Rep. No. 102-384(II), at 11).

A 1991 House Report on Section 340B specifically noted "sharp increases in drug prices to the" Department of Veterans Affairs. H.R. Rep. No. 102-384(I), at 1 (1991). The Committee on Veterans' Affairs "believe[d] that, absent the enactment of legislation which would result in rolling back prices VA pays for needed

pharmaceuticals to levels comparable to those in place prior to [the Omnibus Budget Reconciliation Act of 1990], veterans [would] suffer." *Id.* at 2. "As graphically depicted in [House Report 384(I)], the veteran has become the ultimate and unwitting victim of pharmaceutical companies' circumventing Congress' intent by raising VA prices to protect their profit margins." *Id.* Following these price increases:

> the Co[m]mittee received correspondence from many veterans who wrote to complain that they had received "Dear Veteran" letters informing them that as of a specified date their VA medical center would discontinue filling outpatient prescriptions for specified drugs as an economy measure. Some centers responded to the pharmacy budget dilemma which these price increases posed by substituting lower cost drugs for higher cost medications or even by denying outpatient medications to nonservice-connected veterans altogether.

Id. at 6. The VA Secretary testified before Congress that, to make up for an estimated $60 million annual increase in drug acquisition costs per year, the VA would likely need to "cut programs" and "[c]lose beds." *Id.* at 7.

Congress's goal was that "the 340B program would 'enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Genesis Health Care*, 2023 WL 7549156, at *1 (quoting H.R. Rep. 102-384(II), at 12) (alteration in original). In other words, Congress wanted to ensure certain healthcare providers can afford to provide the care that qualifies an entity to be a covered entity under § 256b. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996) (hereinafter "August 1996 Guidance") (discussing how covered entities could "use savings

realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies"). Section 256b(a)'s text plainly exhibits that purpose by requiring that manufacturers offer covered entities discounts. *See* § 256b(a)(1)–(4). And by "stretch scarce Federal resources," House Report 102-384(II) presumably referred to the fact that many covered entities are federally funded. *See Genesis Health Care*, 2023 WL 7549156, at *1, *10; H.R. Rep. No. 102-384(II), at 7 ("The purpose of H.R. 2890 is to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients.").[1]

Section 340B contains two provisions that prohibit covered entities from abusing their ability to obtain discounted drugs. Covered entities cannot "resell or otherwise transfer" discounted drugs "to a person who is not a patient of the entity." § 256b(a)(5)(B). Covered entities also cannot obtain "duplicate discounts or rebates," meaning they cannot obtain Medicaid rebates under title XIX of the Social Security Act, *see* 42 U.S.C. § 1396, *et seq.*, for drugs that they purchase at a discount under Section 340B, *see* § 256b(a)(5)(A)(i).

To ensure covered entities do not resell discounted drugs or obtain duplicate discounts, the statute contains an auditing provision. It states:

[1] Although a different provision of the same Act specifically addresses prescription drugs acquired by the VA, *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603, 106 Stat. 4943, 4971 (1992); 38 U.S.C. § 8126, the historical context recorded in House Report 384(I) illustrates why Congress provided discounts to covered entities, thus clarifying Congress's purposes and objectives, *see infra*, Part II.B. and note 3.

> A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

§ 256b(a)(5)(C). And "[i]f the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing," that the covered entity illegally resold discounted drugs or obtained duplicate discounts, "the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug . . . provided under the agreement between the entity and the manufacturer." § 256b(a)(5)(D).

The Secretary can impose additional sanctions. Covered entities that the Secretary finds knowingly and intentionally resold discounted drugs must "pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under [§ 256(a)(5)(D)]." § 256b(d)(2)(B)(v)(I). Where the Secretary finds the covered entity's reselling "was systematic and egregious as well as knowing and intentional," the Secretary can remove the covered entity from the program entirely. § 256b(d)(2)(B)(v)(II).

B. The dispensation of 340B drugs at contract pharmacies and related litigation

The issue in this case concerns a matter notably absent from the foregoing discussion: how discounted drugs under Section 340B are delivered to patients of covered entities. *See* August 1996 Guidance at 43,549 ("The statute is silent as to permissible drug distribution systems."). Section 340B does discuss distribution,

directing the Secretary to "establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs," and providing, "*If* a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution." § 256b(a)(8) (emphasis added). These provisions do not mandate how delivery is to occur. And § 256b(a)(8) does not expressly permit or forbid covered entities to pay for drugs to be delivered or dispensed to patients off their physical premises.

HRSA has attempted to fill the statutory silence about delivery with guidance. Between 1996 and March 2010, HRSA's August 1996 Guidance "acknowledged that section 340B 'is silent as to permissible drug distribution systems,' but it nonetheless sought to fill 'gaps in the legislation' and thereby 'move the program forward.'" *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456–57 (D.C. Cir. 2024) (quoting August 1996 Guidance at 43,549–50). Given that "many covered entities use outside pharmacies to distribute drugs to their patients," HRSA's 1996 Guidance "stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457 (citing August 1996 Guidance at 43,555). The August 1996 Guidance also required that, "in directing shipments to its contract pharmacy," the covered entity "must retain title to the drugs and thus 'be responsible' for any diversion or duplicate discounts." *Id.* (citing 1996 Guidance at 43,553).

The August 1996 Guidance did not conclude that use of a contract pharmacy, in and of itself, constitutes illegal diversion under § 256b(a)(5)(B). *See* August 1996

Guidance at 43,549–50 ("If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance."); *see also id.* (explaining how, because "[t]he statute is silent as to permissible drug distribution systems," and "[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself," that "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities"). The August 1996 Guidance responded to extensive comments concerning "[p]otential [d]rug [d]iversion." *Id.* at 43,552. HRSA ultimately concluded that risks of diversion did not warrant precluding covered entities without in-house pharmacies from dispensing 340B drugs that they purchase at a contract pharmacy, and it noted how "[a]lthough some manufacturers expressed concerns regarding the potential for drug diversion, the Department ha[d] received no evidence of diversion that has required an official Departmental investigation." *See id.* at 43,549, 43,552.

HRSA also noted that, while its guidelines would require that "only one site [be] used for" contract pharmacy services, the Office of Drug Pricing ("ODP") would "be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor." *Id.* at 43,555. The August 1996 Guidance appears to have set forth guidelines in the way of compromise, not an interpretation that the statute's silence about delivery implies a one-pharmacy limit for covered

entities without in-house pharmacies. *See id.* at 43549–50 (referring to its proposal as "guidelines" issued because "there were many gaps in the legislation and some form of program structure was necessary to move the program forward").

In 2010, HRSA decided it was no longer appropriate for its guidelines to limit the number of contract pharmacies that covered entities could use. HRSA's 2010 Guidance took the position that "covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Novartis*, 102 F.4th at 457 (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) (hereinafter "2010 Guidance")). In its view, this Guidance "would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients." 2010 Guidance at 10,273. HRSA also explained how, "[s]ince 2001, covered entities that have wanted to use other types of arrangements, or to blend the method of providing services (e.g. contract pharmacy to supplement an in-house pharmacy)," which would go beyond the August 1996 Guidance, "have needed to apply to the [Office of Pharmacy Affairs] for an Alternative Methods Demonstration Project (AMDP) and secure approval in order to proceed." *Id.* "Upon review of the evidence" it collected from these demonstration projects, "HRSA [did] not find sufficient basis to continue limiting contract pharmacies to a single site." *Id.*

In its 2010 Guidance, HRSA did not change its view that covered entities "must maintain title to and responsibility for the drugs." *Novartis*, 102 F.4th at 457 (citing 2010 Guidance at 10,277). HRSA considered comments following the release of proposed guidelines in 2007, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 72 Fed. Reg. 1,540 (Jan. 12, 2007) (hereinafter "2007 HRSA Notice"), asserting that allowing covered entities to dispense Section 340B drugs through multiple contract pharmacies would enable diversion and duplicate discounts, *see* 2010 Guidance at 10,272–75. But it ultimately decided that covered entities could use multiple contract pharmacies if "they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition," including that "[a]uditable records must be maintained to demonstrate compliance with those requirements." *Id.* at 10,273.

In 2020, many pharmaceutical manufacturers sought to prevent covered entities from using multiple contract pharmacies to dispense Section 340B drugs by implementing policies "limit[ing] the number and kinds of contract pharmacies to which they would ship orders." *Novartis*, 102 F.4th at 458. As Plaintiffs argue in their Memorandum [9], pharmaceutical manufacturers were and remain concerned about the model covered entities and contract pharmacies often use in dispensing and accounting for Section 340B drugs. *See* Mem. [9] at 17–18. Plaintiffs refer to that model as the "replenishment model." *Id.* Put simply, under this model, a contract pharmacy first dispenses prescription drugs to all its customers from one supply of drugs, which it purchased at full price from the manufacturer. *Id.*

According to Plaintiffs, the pharmacy—or a third-party administrator—determines whether a customer was a covered-entity patient after it dispenses the drug. *Id.* The pharmacy then informs the covered entity of the quantity of drugs it dispensed to the entity's patients. *Id.* The covered entity then places an order of Section 340B drugs in that quantity as a "replenishment" of the drugs dispensed to covered-entity patients. *See id.*

According to Plaintiffs, sometimes the pharmacies or third-party administrators in fact place the order. *Id.* "Surprisingly, a covered entity might not even be aware that the pharmacy is placing this order as the pharmacy (or its third-party vendor) often places such orders." *Id.* (citing Ex. [8-1] at 7, Scheidler Dec., at ¶ 13). But Plaintiffs have not adduced evidence that anyone but the covered entity ever *pays for* replenishment orders, or that pharmacies nakedly place orders on their own behalf for non-340B purposes.

As the D.C. Circuit recognized, "[m]anufacturers," such as Plaintiffs, "have argued that these arrangements lead to unlawful diversion and duplicate discounts." *Novartis*, 102 F.4th at 458. Under the replenishment model, "[t]he covered entity [and] the pharmacy . . . often divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457. So, covered entities and contract pharmacies both have "a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457–58. Conversely, it seems evident that pharmaceutical manufacturers would prefer as few orders of their products be considered discount-eligible as possible.

In 2020, in response to manufacturers' policies limiting distribution to contract pharmacies, HHS issued an advisory opinion stating that pharmaceutical manufacturers were *required* to permit Section 340B drugs to be delivered to an unlimited number of contract pharmacies. *See Sanofi Aventis*, 58 F.4th at 701 (citing HHS Off. Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020), https://perma.cc/L7W2-H597 (hereinafter "2020 Advisory Opinion")). "HHS reasoned that 340B drugs are 'purchased by' a covered entity no matter how they are distributed," and so, "the 'situs of delivery . . . is irrelevant.'" *Id.* at 701 (citing 2020 Advisory Opinion at 1–3). Both the Third and the D.C. Circuits concluded, however, that Section 340B is silent about delivery, and that the federal statute's requirement that manufacturers offer discounts to covered entities did not implicitly permit HHS to mandate that they comply with any delivery practice the covered entities desire. *See id.* at 703–06; *Novartis*, 102 F.4th at 460–63.

In response, states have begun to impose explicitly what HHS had purported to impose by guidance. For example, in 2021, Arkansas enacted Act 1103, which "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying the pharmacy access to a covered entity's 340B drugs," and "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying 340B drug pricing to covered entities who use contract pharmacies for distribution." *Pharm.*

Rsch. & Manufacturers of Am. v. McClain, 95 F.4th 1136, 1143 (8th Cir. 2024) (citing Ark. Code Ann. § 23-92-604(c)).

An association of pharmaceutical manufacturers sought an injunction against enforcement of the Arkansas law on a theory that Section 340B preempts it. *Id.* at 1139–40. The Eighth Circuit disagreed. *Id.* As to field preemption, the Eighth Circuit concluded that "the 340B Program is not so pervasive that Congress left no room for the States to supplement it," given that the statute is "'is silent about delivery' of drugs to patients." *Id.* at 1143 (quoting *Sanofi Aventis U.S. LLC*, 58 F.4th at 703) (other quotation marks and citation omitted). Concerning conflict preemption, because the Arkansas law "does not require manufacturers to provide 340B pricing discounts to contract pharmacies," and "does not set or enforce discount pricing," the Eighth Circuit found that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to the statute's purpose. *Id.* at 1145. In fact, the Eighth Circuit observed that the Arkansas law "assists in fulfilling the purpose of 340B," in that it facilitates the distribution and dispensation of discounted 340B drugs. *Id.*

On April 12, 2024, the Governor of Mississippi signed H.B. 728, which had been enacted by the state legislature. Ex. [22-1] (H.B. 728). House Bill 728 provides that "[a] manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on

behalf of the covered entity." H.B. 728 § 4. The law defines a "340B drug" as a covered outpatient drug "that has been subject to any offer for reduced prices by a manufacturer pursuant to [Section 340B]." H.B. 728 § 2(a). A violation of H.B. 728 constitutes a violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*, *see* H.B. 728 § 5, which provides for both civil and criminal penalties and is enforced by Mississippi's Attorney General, *see* Miss Code Ann. §§ 75-24-9 (covering injunctive relief), 75-24-19 (covering civil penalties for violations of injunctions issued under § 75-24-9, and for knowing and willful violations of the statute), 75-24-20 (covering criminal penalties for knowing and willful violations).

C. Procedural history

On June 18, 2024, Plaintiffs filed a Complaint [1] in this Court seeking a declaratory judgment under 28 U.S.C. § 2201 that H.B. 728 is unlawful and unenforceable. Compl. [1] at 46. They likewise sought temporary, preliminary, and permanent injunctive relief against the Attorney General of Mississippi, enjoining her from enforcing H.B. 728 against Plaintiffs. *Id.* Plaintiffs filed a Motion [8] for Preliminary Injunction on June 19, 2024, arguing that H.B. 728 is preempted under conflict and field preemption, and that it coerces transfers of discounted drugs to private pharmacies such that it amounts to an unconstitutional taking for private use. *See generally* Mem. [9]. Defendant, Mississippi Attorney General Lynn Fitch, ("Defendant") responded on July 8, 2024, Resp. [22]. The Court held a hearing on the Motion [8] on July 12, 2024.

II. DISCUSSION

A party seeking a preliminary injunction must show: "(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable harm if the injunction does not issue, (3) that the threatened injury outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest." *Clark v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 640–41 (5th Cir. 2023); *see* Fed. R. Civ. P. 65. Factors three and four, "[t]he balance-of-harms and public-interest factors[,] merge when the government opposes an injunction." *Career Colleges & Sch. of Texas v. United States Dep't of Educ.*, 98 F.4th 220, 254 (5th Cir. 2024) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). "A preliminary injunction is an extraordinary remedy and should be granted only if the movant has clearly carried the burden of persuasion with respect to all four factors." *Allied Mktg. Grp., Inc. v. CDL Mktg., Inc.*, 878 F.2d 806, 809 (5th Cir. 1989).

Plaintiffs cannot satisfy the first requirement because they have not demonstrated a "substantial likelihood of success on the merits." *Clark*, 74 F.4th at 640. The Court will therefore deny the Motion [8] and need not reach the other elements.

A. Preemption generally

The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the

Contrary notwithstanding." Art. VI, cl. 2. "Under this principle, Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012).

When a party raises preemption, "'[t]he purpose of Congress is the ultimate touchstone' of [the] analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)) (other citations and quotations omitted). Preemption may be "compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (internal quotation marks and citation omitted). But the Court cannot "assume[] lightly that Congress has derogated state regulation, but instead [should] address[] claims of pre-emption with the starting presumption that Congress does not intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995). And "[d]eference to our federalism counsels a presumption that areas of law traditionally reserved to the states . . . are not to be disturbed absent the clear and manifest purpose of Congress." *In re Davis*, 170 F.3d 475, 481 (5th Cir. 1999) (en banc) (internal quotation marks and citations omitted).

Three categories of preemption exist: "when (1) a federal statute expressly preempts state law," ("express preemption"); "(2) federal legislation pervasively occupies a regulatory field," ("field preemption"); "or (3) a federal statute conflicts with state law," ("conflict preemption"). *Deanda v. Becerra*, 96 F.4th 750, 760–61 (5th Cir. 2024) (citing *Arizona*, 567 U.S. at 398–400). Plaintiffs do not contend that

the 340B Program expressly preempts Mississippi law. *See generally* Mem. [9]. Rather, Plaintiffs argue that the 340B Program implicitly preempts Mississippi law under conflict preemption and field preemption. *Id.* at 13–19.

B. Section 340B does not preempt H.B. 728 under conflict preemption

Conflict preemption arises "where 'compliance with both state and federal law is impossible,' or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (quoting *California v. ARC America Corp.*, 490 U.S. 93, 100, 101 (1989)) (other internal quotation marks omitted). "In either situation, federal law must prevail." *Id.*

Plaintiffs do not contend that compliance with both Mississippi and federal law is impossible. *See generally* Mem. [9]. So, Plaintiffs must show that the Mississippi law "produce[s] a result inconsistent with the objective of the federal statute," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such that it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941). Plaintiffs must cross "a high threshold" to succeed on such a theory. *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023) (quoting *Chamber of Com. v. Whiting*, 563 U.S. 582, 607 (2011)), *cert. denied*, 144 S. Ct. 557 (2024). "Courts may not conduct 'a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives [because] such an endeavor would undercut the principle

that it is Congress rather than the courts that pre-empts state law.'" *Id.* (quoting *Whiting*, 563 U.S. at 607) (alteration in original).

In a case like this one, "[p]reemption analysis begins 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Deanda*, 96 F.4th at 761 (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). That is because a state law regulating health and safety falls within a state's traditional police powers. *See Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 710, 716 (1985) (holding that a local regulation of blood donation centers, including "donor testing and recordkeeping requirements beyond those contained in the federal regulations," was not preempted because the challenger did not "present a showing of implicit pre-emption of the whole field, or of a conflict between a particular local provision and the federal scheme, that [was] strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation"); *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796, 813 (5th Cir. 2011) (discussing how the Court should "begin with the assumption that Congress did not intend to supersede the historic police powers of the states to protect the health and safety of their citizens" (internal quotation marks and citation omitted)).

House Bill 728 plainly falls under the umbrella of a health and safety regulation. It prohibits manufacturers from refusing to deliver Section 340B drugs to contract pharmacies, presumably to maximize covered-entity patients' access to

drugs for which the manufacturers have already agreed to provide a discount. The state statute therefore triggers the presumption against preemption. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (plurality opinion of Stevens, J.) (applying "[t]he presumption against federal pre-emption of a state statute designed to foster public health" (citing *Hillsborough Cnty.*, 471 U.S. at 715–18), and rejecting a preemption claim challenging a Maine policy that subjected drug manufacturers' pharmaceuticals to prior authorization procedures before providing state Medicaid coverage for them unless the manufacturers agreed to provide rebates to Maine residents beyond rebates the Medicaid Act provides for); *Wyeth v. Levine*, 555 U.S. 555, 578 (2009) ("[T]he FDA traditionally regarded state law as a complementary form of drug regulation."); *McClain*, 95 F.4th at 1144 (holding that Section 340B does not preempt state law prohibiting manufacturers from precluding covered entities from making dispensation contracts with pharmacies in part because "[p]harmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted").

Plaintiffs argue that the law does not trigger this presumption, but the Court is unpersuaded. *See* Reply [25] at 7. Plaintiffs cite *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012), but *Lofton* merely states that "whatever value or relevance a presumption against preemption of state tort law should play is uncertain" given its observation that the Supreme Court's "majority

opinion in [*PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)] made no reference to the 'presumption' in the course of upholding implied conflict preemption over state law claims for failure to maintain adequate warning labels for FDA-approved generic drugs." 672 F.3d at 378. *Lofton*'s statements about the scope of the presumption against preemption do not mean that the presumption against preemption no longer applies.

Further, *Lofton*'s note that "the primacy of the state's police powers is not universal" does not alter whether the presumption against preemption applies. *Id.* *Lofton* discussed state-law tort claims based on fraud on the FDA. *See id.* at 378–79. In that context, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 378 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001)). House Bill 728 does not purport to prohibit fraud on a federal agency.

Plaintiffs also argue that the presumption against preemption does not apply because H.B. 728 "explicitly depends on a federal statute," Section 340B, and "imposes additional terms and conditions on drug manufacturers' 340B arrangements with the federal government." Reply [25] at 7. The argument is essentially that, by regulating the delivery of drugs discounted under a federal program, Mississippi is in effect amending a federal regulation, not enacting its own health and safety regulation under its police powers. But the Fifth Circuit has explained how, even when a given field is "an area of significant federal presence," a

state law regulating the same subject matter can be "grounded instead in consumer protection, an area traditionally reserved to the States," and thus entitled to the presumption against preemption. *Teltech Sys., Inc. v. Bryant*, 702 F.3d 232, 236 (5th Cir. 2012).

Notably, the Supremacy Clause's text does not indicate that states cannot regulate by reference to pre-existing federal programs. The Clause provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2. This language indicates federal law governs despite a conflict with state law, but not that states lack the power to enact regulations by reference to federal law. *See McCulloch v. Maryland*, 4 Wheat. 316, 361 (1819) ("By this declaration, the states are prohibited from passing any acts which shall be repugnant to a law of the United States."). True, "[s]tates have no power . . . to retard, impede, burden, or in any manner control the operations of the constitutional laws enacted by Congress." *Trump v. Vance*, 140 S. Ct. 2412, 2425 (2020) (citing *McCulloch*, 4 Wheat. at 436). But the authorities cited show that state laws that do not conflict with the federal law are constitutional.

Applying the presumption against preemption here, the Court does not find that Section 340B exhibits a clear purpose to preempt state laws that would require manufacturers to deliver covered entities' drugs to contract pharmacies for dispensation. Section 340B does not explicitly mandate how delivery of discounted drugs is to occur. *See McClain*, 95 F.4th at 1142 ("[T]he 340B Program 'is silent

about delivery' and distribution of pharmaceuticals to patients." (quoting *Sanofi Aventis*, 58 F.4th at 703)). Section 340B merely requires participating manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." § 256b(a)(1). And it prohibits the resale of those discounted drugs to anyone "who is not a patient of the entity." § 256b(a)(5)(B).

Sanofi Aventis and *Novartis* concluded that, under the terms of Section 340B, HHS may not *require* manufacturers to ship drugs intended for covered-entity patients to any contract pharmacy the entity deals with. *Sanofi Aventis*, 58 F.4th at 703 (concluding that "Section 340B does not require delivery to an unlimited number of contract pharmacies"); *Novartis*, 102 F.4th at 460–63. But the same "[s]tatutory silence[]," *Sanofi Aventis*, 58 F.4th 699, that does not *implicitly mandate* that manufacturers deliver to any contract pharmacy does not, on the other hand, show that Congress clearly intended to *preclude states* from enacting their own public health regulations aimed at maximizing the availability of low-cost drugs for covered-entity patients, *see McClain*, 95 F.4th at 1145 (concluding that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to Section 340B's objectives). If anything, H.B. 728 arguably promotes Section 340B's objective by ensuring covered-entity patients can conveniently access 340B drugs. *See id.* at 1144–45 (explaining how Arkansas's prohibition on manufacturers preventing covered entities from contracting with pharmacies for drug distribution "does not create an obstacle for pharmaceutical

manufacturers to comply with 340B, rather it does the opposite: [the law] assists in fulfilling the purpose of 340B").

Even if most covered-entity patients who obtain discounted drugs at contract pharmacies have insurance that reimburses the pharmacy—which passes on the reimbursement to the covered entity, less service and administrative fees, *see* Ex. [24-20] at 19—*some* patients lack insurance and rely on 340B discounts at pharmacies. Plaintiffs cite a study based on an analysis of pharmacy claims data that found 1.4% of contract-pharmacy dispensations of branded 340B drugs were to patients using "340B discount cards," which are cards pharmacies give to uninsured covered-entity patients. Ex. [24-10] at 8–12. On average, patients with these cards received a 92.9% discount. *Id.* at 11. Of other dispensations, 50.8% were paid by Medicaid or Medicare coverage, and 39.0% were paid by commercial insurance. *Id.*

To support its argument that, at least in Mississippi, contract pharmacies benefit patients, Defendant submitted the Declaration of Trenton Deland Lott, Pharm.D., A.C.E., "a Managing Member and co-founder of 340B Together, LLC, which provides management services to 340B covered entities." Ex. [22-7] at 1. He declared that use of contract pharmacies "enables 340B entities to provide medications to needy Mississippians across a wider geographic area than is currently permitted under AbbVie's recently adopted restrictions," which limit covered entities to a single contract pharmacy within 40 miles of the entity. *Id.* at 2. He emphasized how covered-entity patients may struggle to transport themselves to the covered entity's in-house pharmacy or a far-away contract

pharmacy, rendering it more difficult for them "to obtain needed pharmaceuticals in a timely fashion." *Id.* He also stated that "[t]he Mississippi 340B hospitals and other covered entities with which [he] work[s] routinely pass on 340B savings to 340B qualified patients without third-party coverage in the form of cash cards to be used when purchasing 340B drugs." *Id.*

The Court does not find, at this juncture, that Plaintiffs have shown that patients do not benefit from contract pharmacies through H.B. 728. Regardless, Congress also intended that Section 340B would incentivize providers to provide certain kinds of care by ensuring they can obtain drugs for their patients at discounted prices. *See Am. Hosp. Ass'n*, 596 U.S. at 730, 738; *Genesis Health Care*, 2023 WL 7549156, at *1 (citing H.R. Rep. 102-384(II) at 12). The history behind the statute illustrates that Congress passed it out of concern for covered entities' margins, and that covered entities' margins affect patient care. *See supra*, Part I.A.

Plaintiffs cite several studies and reports arguing that Section 340B does not sufficiently ensure that covered entities use the margins they obtain through the program to serve patients, and that covered entities focus expansion of services and contract pharmacies in areas mostly inhabited by insured patients to maximize their margins.[2] *See* Ex. [24-3] at 6; Ex. [24-4] at 3; Ex. [24-5] at 2; Ex. [24-6] at 3–5; Ex. [24-7] at 3; Ex. [24-8] at 2–3; Ex. [24-9] at 1–4; Ex. [24-10] at 12; Ex. [24-14] at 8. But criticism of Section 340B's effectiveness in achieving its *own* purposes cannot

[2] Plaintiffs included these reports at least in part to argue that enjoining enforcement H.B. 728 will not disserve the public interest. *See Clark*, 74 F.4th at 640–41 (outlining the preliminary injunction factors).

give rise to a conflict-preemption claim when the state statute is not inconsistent with Section 340B's terms. *See Barrosse*, 70 F.4th at 320 ("Courts may not conduct 'a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives [because] such an endeavor would undercut the principle that it is Congress rather than the courts that pre-empts state law.'" (quoting *Whiting*, 563 U.S. at 607)) (alteration in original).

The upshot of Plaintiffs' argument that Section 340B and H.B. 728 conflict is that Congress deliberately left to pharmaceutical manufacturers the discretion to refuse to ship 340B discounted drugs to contract pharmacies simply because it was silent in the statute about delivery. *See* Reply [25] at 8 (citing *Sanofi Aventis*, 58 F.4th at 704; *Novartis*, 102 F.4th at 460). True, federal law can preempt state law when Congress, or a federal agency implementing federal law, makes a policy choice that balances competing objectives in such a way that a state regulation aimed at the same subject matter upsets the balance that the federal government struck. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000). But that is not this case.

In *Geier*, for example, the Court held that a Department of Transportation regulation, FMVSS 208, requiring automobile manufacturers to equip some, but not all, of their 1987 vehicles with passive restraints—such as airbags—preempted state tort law requiring airbags beyond what that regulation required. 529 U.S. at 864–65. But there, the Supreme Court found that "clear evidence of a conflict" existed between state tort law and the regulation. *Id.* at 885. The Court reached this conclusion based on the agency's "contemporaneous explanation" of several

"significant considerations" it had in mind in designing the regulation. *See id.* at 877–81. The regulation "deliberately provided [car manufacturers] with a range of choices among different passive restraint devices," so as to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 875.

Here, Plaintiffs do not persuasively show, at least at this stage of the proceedings, how H.B. 728 creates a substantial obstacle to Section 340B's purposes, or what consideration Congress had in mind in not addressing delivery of 340B drugs. In other words, there is no clear evidence of an "actual," "significant" conflict. *Id.* at 884–85 (internal quotation marks and citation omitted). House Bill 728 does not require pharmaceutical manufacturers to offer 340B drugs below applicable ceiling prices, expand the definition of what a 340B healthcare provider is, or expand the remedies available to a covered entity when a manufacturer overcharges it for 340B drugs. House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to pharmacies for dispensation—something § 256b neither requires nor precludes.

To the extent that delivering discounted drugs to contract pharmacies raises the risk of diversion, Section 340B prohibits diversion and provides for comprehensive enforcement mechanisms. *See supra*, Part I.A. If Section 340B healthcare providers are conspiring with pharmacies to divert discounted drugs, HHS can require the provider to compensate the manufacturer for its losses, § 256b(a)(5), and remove the provider from the program, § 256b(d)(2)(B)(v)(II). The

Court is not prepared to find Section 340B likely preempts H.B. 728 on a theory that Congress's remedial scheme under Section 340B is inadequate to deter violations of federal law. As written, H.B. 728 and Section 340B do not conflict.

Congress also increased enforcement mechanisms against diversion in the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102, 124 Stat. 119 (enacted March 23, 2010), by adding § 256b(d), *id.* at 823–26, which was enacted 18 days after the 2010 HRSA Guidance that advised that covered entities can use an unlimited number of contract pharmacies, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010). Congress also added several categories of hospitals as covered entities. Pub. L. No. 111-148, 124 Stat. 821–822; 42 U.S.C. § 256b(a)(4)(M)–(O). Thus, Congress was presumably aware of potential risks of diversion through the use of contract pharmacies, and it expanded Section 340B while increasing enforcement against diversion. Yet Congress remained silent about delivery—not to mention about preemption. And while "failures to enact legislation 'are not reliable indicators of congressional intent,'" *Novartis*, 102 F.4th at 462 (quoting *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989)), Plaintiffs' argument relies on an inference of preemptive intent from Congress's silence as to delivery, so the Court considers legislative context relevant in interpreting that silence, *see Arizona*, 567 U.S. at 405–406 (discussing policy proposals Congress did not enact in analyzing preemption).[3]

[3] Ordinarily, it is the party claiming preemption that will "rely on legislative history to demonstrate

In addition, Plaintiffs argue that H.B. 728 "conflicts with" Section 340B's enforcement provisions "by creating its own enforcement scheme entirely separate and apart from federal law." Mem. [9] at 17. The Court disagrees: H.B. 728 addresses delivery and Section 340B does not, so adjudications under H.B. 728 will not interfere with federal enforcement of Section 340B's compliance mechanisms.

Plaintiffs further argue that H.B. 728's terms literally require manufacturers to sell drugs at discounts directly to private pharmacies. Plaintiffs point out how H.B. 728 requires "that '[a] manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, *the acquisition of a 340B drug by*, or delivery of a 340B drug to, *a pharmacy* that is under contract with a 340B entity.'" Mem. [9] at 17 (quoting H.B. 728 § 4(1)) (Plaintiffs' emphasis and alteration). Plaintiffs argue that the term "acquisition" means H.B. 728 compels direct sales to pharmacies, not covered entities.

The Court cannot agree. House Bill 728 defines a "340B drug" as "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to use pursuant to 42 USC 256b and is purchased by a covered entity as defined in 42 USC 256b(a)(4)." H.B. 728 § 2(a). Incorporating this definition into § 4(1), H.B. 728 prohibits manufacturers from interfering with delivery of drugs "purchased by a

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Congress" intended to preempt state law by inaction. *TelTech*, 702 F.3d at 238. For that reason, Justice Thomas has noted his skepticism of purposes and objectives preemption, arguing that, under it, "the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law." *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring in the judgment).

covered entity" to contract pharmacies. *Id.* If the drugs are not purchased by a covered entity, § 4(1) does not apply.

Further, § 4(1)'s terms "should be 'interpreted in [their] statutory and historical context and with appreciation for [their] importance to the [statute] as a whole.'" *Texas v. Biden*, 646 F. Supp. 3d 753, 767 (N.D. Tex. 2022) (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 471 (2001)), *appeal dismissed*, No. 23-10143, 2023 WL 5198783 (5th Cir. May 25, 2023). The rest of H.B. 728 § 4(1) plainly addresses delivery. Section 4(1) discusses the pharmacy's contract with a 340B entity, confirming that it addresses distribution of drugs, not sale of drugs directly to pharmacies. *See* H.B. 728 § 4(1). And if the Mississippi Legislature meant to use H.B. 728 to require manufacturers to sell drugs at 340B discounts to private pharmacies, it could have straightforwardly borrowed the phrase "shall . . . offer" from § 256b(a)(1), rather than deploy the phrase "deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by . . . a pharmacy under contract with" a covered entity. H.B. 728 § 4(1).

The history behind H.B. 728, *see supra*, Parts I.A.–B., further demonstrates that Mississippi passed the law to fill the gap in Section 340B concerning delivery of Section 340B drugs. HRSA recognized early on how "Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." August 1996 Guidance at 43,549. House Bill 728's broad language is thus reasonably read as ensuring manufacturers

do not craft creative distribution schemes or conditions to avoid providing discounts on 340B drugs.

Further, H.B. 728 states that it should not be construed to conflict with federal law, H.B. 728 § 6, and the Court must apply the presumption against preemption to construe state laws not to conflict with federal law when possible, *see Fox v. Washington*, 236 U.S. 273, 277 (1915) ("So far as statutes fairly may be construed in such a way as to avoid doubtful constitutional questions they should be so construed; and it is to be presumed that state laws will be construed in that way by the state courts." (citation omitted)). The Court will not read H.B. 728 § 4(1) to accidently conflict with federal law.

The Court finally addresses Plaintiffs' argument that H.B. 728 conflicts with § 256b(a)(5)(B) because it compels manufacturers to cooperate with the replenishment model. *See* Mem. [9] at 17–18; *supra*, Part I.B. (explaining the replenishment model). Plaintiffs assert that replenishment orders are, in and of themselves, illegal diversion. *See* Mem. [9] at 17–18. Plaintiffs' theory is that the covered entity purchases the replenishment supply at the Section 340B discount for delivery to the pharmacy, which places the drugs on its shelf in a commingled supply for dispensation to its next customer, who may be "a person who is not a patient of the [covered] entity." § 256b(a)(5)(B).

Although that may be true in a literal sense, the Court does not find that the replenishment model constitutes illegal diversion. As Plaintiffs' Exhibit [24-17], which is a copy of Intervenor Defendant's Reply in Support of Its Motion for

Summary Judgment in *AbbVie et al. v. Murrill*, No. 6:23-cv-1307-RRS-CBW (April 26, 2024), ECF No. 74, explains:

> Replenishment inventory systems are commonplace. When a manufacturer sells drugs through a wholesaler, the drugs shipped to the wholesaler are not intended to fill a particular order placed by a pharmacy; instead, they supply inventory to the wholesaler that the wholesaler then sells to a pharmacy. *See, e.g.*, Robert Handfield, Biopharmaceutical Supply Chains 11-13 (2012) (ebook). Even if the drugs shipped by the manufacturer to the wholesaler filled an order placed by a pharmacy, the drugs would not necessarily be the same drugs delivered by the wholesaler to the pharmacy because prescription drugs are manufactured in a precise and reproducible manner that make them fungible. *See* 21 U.S.C. §§ 360(e), 360eee-1; 21 C.F.R. § 207.33.

Ex. [24-17] at 11. Accordingly, it appears that pharmaceuticals distribution often relies on pharmaceuticals' fungibility to facilitate efficiency. So, Section 340B presumably contemplates that efficient distribution of fungible drugs to covered-entity patients might utilize a replenishment model.

Importantly, Section 340B's terms in no way prohibit the use of contract pharmacies. Section 340B mandates that manufacturers "offer" discounted drugs to covered entities, § 256b(a)(1), and prohibits covered entities from diverting those drugs to persons who are not their patients, § 256b(a)(5)(B). While § 256b discusses distribution options, directing the Secretary to "establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs," and providing, "*If* a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution," § 256b(a)(8) (emphasis added), § 256b does not mandate how delivery must occur. HRSA has also taken the position since 1996 that "[i]f [a

covered] entity directs [a] drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." August 1996 Guidance at 43,549–43,550. HRSA even noted the following comment and response:

> Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs. By issuing guidelines in this area, ODP is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.
>
> Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion [and duplicate discounts].

Id. Given that § 256b's text does not prohibit distribution through contract pharmacies, and that such distribution has long been understood not to constitute diversion, the Court does not find that the replenishment model, which facilitates that distribution, can be undercut by technicality.

All told, the Court concludes that Plaintiffs have not shown a substantial likelihood that they will succeed on the merits of a conflict-preemption claim.

C. Section 340B does not preempt H.B. 728 under field preemption

The Court is also unpersuaded that Section 340B preempts H.B. 728 under a theory of field preemption. Field preemption requires that Congress has passed such comprehensive legislation in an area that it has "occupied the field." *Arizona*, 567 U.S. at 401. Congress's intent to displace state law can be inferred from its

enactment of a federal regulatory scheme "'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id.* at 399 (quoting *Rice*, 331 U.S. at 230). Field preemption "should not be inferred, however, simply because the agency's regulations are comprehensive." *R.J. Reynolds Tobacco Co. v. Durham Cnty., N.C.*, 479 U.S. 130, 149 (1986).

"Field preemption of state law is disfavored." *Nat'l Press Photographers Ass'n v. McCraw*, 90 F.4th 770, 796 (5th Cir. 2024). The Fifth Circuit has emphasized that "Courts should not infer field preemption in 'areas that have been traditionally occupied by the states,' in which case congressional intent to preempt must be 'clear and manifest.'" *Id.* (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). "And importantly, field preemption is not to be found where federal 'regulations, while detailed, appear to contemplate some concurrent state regulation.'" *Id.* (quoting *R.J. Reynolds Tobacco*, 479 U.S. at 149).

House Bill 728 implicates public health and welfare, a traditional area of state regulation, triggering the presumption against preemption, *see supra*, Part II.B., and rendering inapplicable *Arizona*'s discussion of dominant federal interests, *see Arizona*, 567 U.S. at 399. While H.B. 728 surely regulates in "an area of significant federal presence," that does not preclude the application of the presumption against preemption. *Teltech*, 702 F.3d at 236. Every plausible case of field preemption must involve significant federal regulation. Significant federal

regulation cannot turn traditional areas of state authority into areas dominated by federal interests, *see Arizona*, 567 U.S. at 399, if "field preemption is not to be found where federal 'regulations, while detailed, appear to contemplate some concurrent state regulation,'" *Nat'l Press Photographers Ass'n*, 90 F.4th at 796 (quoting *R.J. Reynolds Tobacco*, 479 U.S. at 149).

Section 340B contemplates concurrent state regulation. The statute does not control how covered entities or manufacturers must deliver discounted drugs to patients of covered entities. *See supra*, Part II.B. Section 340B thus leaves room for states to impose their own regulations on delivery of Section 340B drugs to promote patients' access to their medications. "[M]erely because [Section 340B is] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field." *Hillsborough Cnty.*, 471 U.S. at 717.

While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs and provides robust enforcement mechanisms that ensure covered entities and manufacturers comply with the statute's requirements, *see supra*, Part I.A., Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs. In fact, as far back as its August 1996 Guidance about dispensation at contract pharmacies, HRSA observed that "[d]uring the early months following enactment, it became clear that there were many gaps in the legislation," demonstrating that the statute is not sufficiently comprehensive to give rise to field preemption. August 1996 Guidance at 43,549.

The Court is also not persuaded that field preemption is compelled by *Astra*'s holding that covered entities cannot bring overcharging claims as third-party beneficiaries to PPAs. *See Astra*, 563 U.S. at 117–19. *Astra* rejected an argument that, despite a covered entity's "inability to assert a statutory right of action" under Section 340B itself, "PPAs implementing the 340B Program are agreements enforceable by covered entities as third-party beneficiaries." *Astra*, 563 U.S. at 117. Because PPAs are essentially contracts whereby manufacturers opt into Section 340B, the Court reasoned that "[a] third-party suit to enforce an HHS-drug manufacturer agreement, therefore, is in essence a suit to enforce the statute itself." *Id.* at 118. Accordingly, "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead." *Id.*

The Supreme Court's rejection of a right of action for covered entities under PPAs has minimal bearing on whether Section 340B preempts state law about the delivery of 340B drugs. And *Astra* did not apply any presumption in favor of such a right of action analogous to the presumption against preemption applicable here. *See Arizona*, 567 U.S. at 400 ("In preemption analysis, courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." (internal quotation marks and citations omitted)). The Court therefore concludes that Plaintiffs have not shown a substantial likelihood of success on the merits of their field preemption claim.

D. House Bill 728 is not an unconstitutional taking

Plaintiffs next contend that "H.B. 728 effects an unconstitutional taking because it requires drug manufacturers to give their property to other private parties, for free, and not for any recognized public use." Mem. [9] at 3. The Court disagrees.

1. The Takings Clause generally

The Takings Clause of the Fifth Amendment, which is "applicable to the States through the Fourteenth Amendment," *Cedar Point Nursey v. Hassid*, 594 U.S. 139, 147 (2021), provides: "[N]or shall private property be taken for public use, without just compensation," U.S. Const. amend. V. Takings claims are cognizable as to both personal property, including goods, and real property. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015). A taking can be *per se* or regulatory, both of which entitle the property owner to just compensation. *Cedar Point Nursey*, 594 U.S. at 147–49. A *per se* taking occurs "[w]hen the government physically acquires private property for a public use," including "when the government physically takes possession of property without acquiring title to it." *Id.* at 147.

A taking can also occur by virtue of "the deprivation of the former owner rather than the accretion of a right or interest to the sovereign." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005–06 (1984) (internal quotation marks and citation omitted). To that end, a regulation constitutes a taking when it "goes too far" in limiting an owner's use of her property. *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922).

To determine whether a regulation amounts to a taking, courts apply "the flexible test developed in" *Penn Central Transportation Company v. City of New York*, 438 U.S. 104 (1978). *Cedar Point Nursey*, 594 U.S. at 148. The *Penn Central* test requires "balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action." *Id.* A regulation that deprives a property owner of "*all* economically beneficial uses" of her property constitutes a regulatory taking. *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1019–20 (1992) (emphasis in original) (finding a regulatory taking, and thus requiring just compensation, when enforcement of a "coastal-zone construction ban" rendered beachfront property "valueless").

Regardless of whether the government pays just compensation for a taking, however, property may only "be taken for *public* use." U.S. Const. amend. V (emphasis added). The Supreme Court has held that the phrase "public use" requires that the taking "serve[] a 'public purpose.'" *Kelo v. New London*, 545 U.S. 469, 480 (2005). The Supreme Court has "defined that concept broadly, reflecting [the Court's] longstanding policy of deference to legislative judgments" in redevelopment of property, and in "a purely economic context" as well. *Id.* at 480–82 (citing *Berman v. Parker,* 348 U.S. 26 (1954), *Hawaii Hous. Auth. v. Midkiff,* 467 U.S. 229 (1984), and *Monsanto,* 467 U.S. at 1014). While recognizing that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation," *Kelo* upheld a

taking for economic development by private businesses that included a research facility for Pfizer—a pharmaceutical company—restaurants, and shops. *Id.* at 473–77.

As Plaintiffs point out, both states and the federal government are free to bargain with private parties. When private parties "voluntarily accept responsibilities under" federal law because "they consider it in their best interest to do so," no taking occurs. *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991). Under this principle, "[g]overnmental regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *Id.* (internal quotation marks and citations omitted). To that end, a "state law limiting fees that nursing homes voluntarily participating in Medicaid may charge non-Medicaid patients effects no taking '[d]espite the strong financial inducement to participate in Medicaid.'" *Id.* (quoting parenthetically *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied,* 469 U.S. 1215 (1985)).

While the principle that no taking occurs in a voluntary exchange appears to exist independently of any *Penn Central* analysis, *see id.*, the Supreme Court has also applied *Penn Central* to determine whether a voluntary exchange with the federal government constituted a taking. In *Monsanto*, the Supreme Court rejected in part a takings challenge to the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 61 Stat. 163, *as amended*, 7 U.S.C. § 136,

et seq. 467 U.S. at 1006–08. The 1978 amendments to FIFRA allowed the Environmental Protection Agency ("EPA") to disclose trade secrets contained in applications for licenses to sell pesticides ten years after the applicant filed its application. *See id.* The Court rejected the takings claim to the extent an applicant was "aware of the conditions under which the data [were] submitted" because "a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking." *Id.*

Monsanto framed the issue under the *Penn Central* test. *See id.* at 1005–06. After reciting the *Penn Central* factors, the Court focused on the third one: the statute's "interference with reasonable investment-backed expectations." *Id.* (quoting *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 83 (1980)). As to submissions of applications after 1978—meaning, those submitted with knowledge of the potential for disclosure of trade secrets contained therein—"the force of [the third] factor [was] so overwhelming" as to be dispositive. *Id.* The Court further concluded that "the conditions [were] rationally related to a legitimate Government interest" in regulating pesticides. *Id.* at 1007.

FIFRA's 1978 amendments also permitted EPA to disclose trade secrets contained in applications submitted before 1978, meaning before any explicit notice of the potential for disclosure. *See id.* at 1008. Because Congress amended FIFRA in 1972 to promise applicants their trade secrets would not be disclosed, *Monsanto* concluded that a taking occurred as to any disclosed trade secrets submitted in applications between 1972 and 1978. *See id.* at 1010–14.

Before the 1972 amendments to FIFRA, however, the statute "was silent with respect to EPA's authorized use and disclosure of data submitted to it in connection with an application for registration." *Id.* at 1008. Notwithstanding that the Trade Secrets Act, 18 U.S.C. § 1905, prohibited federal employees from disclosing trade secrets revealed to them in the course of their official duties, the Court found that "absent an express promise" directed to it—rather than to federal employees—"Monsanto had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA." *Id.* The Court emphasized,

> In an industry that long has been the focus of great public concern and significant government regulation, the possibility was substantial that the Federal Government, which had thus far taken no position on disclosure of health, safety, and environmental data concerning pesticides, upon focusing on the issue, would find disclosure to be in the public interest.

Id. at 1008–09.

Conditions for permits cannot go too far, however. The inquiry turns on "whether the permit condition bears an 'essential nexus' and 'rough proportionality' to the impact of the proposed use of the property." *Cedar Point Nursery*, 594 U.S. at 161 (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)). So, the government cannot "hold hostage, to be ransomed by the waiver of constitutional protection," uses of property that are "basic and familiar." *Horne*, 576 U.S. at 366. In *Horne*, the Court concluded that a requirement that raisin growers turn over large portions of their crops to the government in exchange for "the 'benefit' of being allowed to sell" the rest of the raisins constituted a taking. *Id.* Distinguishing

Monsanto, the Court emphasized that selling produce, unlike selling pesticides, is "not a special governmental benefit that the Government may hold hostage." *Id.*

2. House Bill 728 does not work an unconstitutional taking for private use

Plaintiffs claim H.B. 728 effects a *per se* taking of their pharmaceutical products for private use. They rely on "the most basic principle of takings law . . . that legislatures may not take property from private party A and give it to private party B." Mem. [9] at 20 (citing *Kelo*, 545 U.S. at 477, and *Midkiff*, 467 U.S. at 245). They claim that H.B. 728 does so because it forces pharmaceutical manufacturers subject to Section 340B to sell their products at discounted rates to private pharmacies. They accordingly assert that "a taking occurs each and every time a drug manufacturer is required, against its own volition, to transfer its drugs at the 340B discount price to a commercial pharmacy for the private benefit of that pharmacy." *Id.* at 24. In arguing that H.B. 728 effects private takings, Plaintiffs contend that "H.B. 728 advances no 'public use' recognized in American law." *Id.* at 21.

Plaintiffs also maintain that "the voluntary participation doctrine" is inapplicable here. *Id.* at 22. They acknowledge that, "[u]nder certain circumstances, voluntarily accepting a government benefit in exchange for giving up property rights can extinguish a takings claim against the government who conferred the bargained-for benefit." *Id.* (citing *Monsanto*, 467 U.S. at 1007). But "[their] participation in *federal* Medicare and Medicaid programs—and the assumption of *federal* obligations under the 340B program—cannot justify the

separate *state* requirements H.B. 728 seeks to impose" because "Mississippi provides 'no additional benefit' to AbbVie under H.B. 728." *Id.* (quoting *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023)).

First and foremost, the Court does not agree with Plaintiffs' characterization of H.B. 728 as compelling direct, confiscatory sales from them to private pharmacies. *See supra*, Part II.B. The statute only requires Plaintiffs to offer 340B drugs for purchase by covered entities, § 256b(a)(1), regardless of whether the covered entity will have those drugs delivered and dispensed to its patients at a private pharmacy with which it has an arrangement, *see supra*, Part II.B. Because H.B. 728 does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it does not cause takings for private use according to Plaintiffs' theory. Nor is the Court persuaded that the manner of delivery to covered-entity patients can constitute a *per se* taking: Plaintiffs are still only required to sell at 340B discounts to covered entities, and they can still only have drugs dispensed to their patients.

To the extent that H.B. 728's delivery obligation can be conceptualized as a regulatory limit on Plaintiffs' property rights, it is not a taking under *Penn Central*. *Monsanto*, applying *Penn Central* to a voluntary exchange involving the disclosure of trade secrets contained in license applications, found such disclosure was foreseeable even before Congress amended FIFRA to explicitly warn of disclosure. 467 U.S. at 1008. That states might require Section 340B drugs to be distributed for dispensation at private pharmacies should have been foreseeable to Plaintiffs, as Section 340B has had a well-known "gap" about how delivery must occur since

Congress enacted it. *See* August 1996 Guidance at 43,549–50 (discussing "gaps" in Section 340B including that it "is silent as to permissible drug distribution systems"). Congress's silence left delivery options open because "a matter not covered is not covered." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012) (discussing the *casus omissus* canon).

Plaintiffs rely on HRSA's August 1996 Guidance to show that Section 340B limits dispensation at contract pharmacies, but that Guidance did not purport to find a one-pharmacy limit in the text. HRSA in fact stated that Section 340B contemplates that "various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." August 1996 Guidance at 43,549. HRSA only published "guidelines" in 1996 "to move the program forward," *id.*, and eventually backed off any limit on contract pharmacies after finding "there ha[d] been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program," which permitted use of multiple contract pharmacies and enabled ODP to study their operations, 2007 HRSA Notice at 1,540.

Further, when Congress enacted Section 340B, "only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)," such that the potential for contract pharmacy dispensation was foreseeable. August 1996 Guidance at 43,550. While the August 1996 Guidance's "guideline[]" of one contract pharmacy for covered entities without in-house pharmacies is not consistent with H.B. 728, that same Guidance appears to contemplate that state law might protect

covered entities' "right" to purchase drugs at 340B prices and have them dispensed at multiple pharmacies. *See id.* (*Comment:* "As a matter of State [agency] law, [covered] entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. . . . *Response:* We agree.").

In "an industry," such as pharmaceuticals, "that long has been the focus of great public concern and significant government regulation," enhanced regulation where Congress was previously silent is foreseeable, which cuts against finding a regulatory taking. *Monsanto*, 467 U.S. at 1008–09. Likewise, because Section 340B does not preempt state laws requiring delivery of 340B drugs to contract pharmacies, *see supra*, Parts II.B.–C., Plaintiffs could have foreseen that states might enact policies favoring dispensation at contract pharmacies as well, *see Pace Res., Inc. v. Shrewsbury Twp.*, 808 F.2d 1023, 1033 (3d Cir. 1987) ("[I]nvestment-backed expectations are reasonable only if they take into account the power of the state to regulate in the public interest.").

Further, H.B. 728 is "rationally related to a legitimate Government interest." *Monsanto*, 467 U.S. at 1007. The Mississippi Legislature has evidently determined that dispensation of 340B drugs at contract pharmacies advances public health, which falls squarely within its police powers. *See supra*, Part II.B.

To the extent that dispensation of 340B drugs at contract pharmacies will increase the number of medications for which Plaintiffs must provide discounts, and thus cut into Plaintiffs' profits, "the economic impact of the regulation" is not drastic, *Cedar Point Nursery*, 594 U.S. at 148, and will not deprive Plaintiffs of all

economically beneficial use of their products, *Lucas*, 505 U.S. at 1019–20. Although a small portion of 340B discounts drop the drug price to a penny under particular circumstances,[4] "the average discount rate appears to be between 25 and 50 percent," *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 208 (D.N.J. 2021) *aff'd in part, rev'd in part on other grounds sub nom. Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023); *see* Ex. [24-3] at 6 (discussing the Centers for Medicare and Medicaid Services's estimated average discount on 340B drugs, 34.7%, which excludes "'penny-priced' drugs"); Ex. [24-4] at 4 (same).

Even if H.B. 728 effects a taking, the Court also finds that H.B. 728 is not a private taking, but a taking that "serves a 'public purpose.'" *Kelo*, 545 U.S. at 480. The Supreme Court has defined the concept of a public purpose "broadly, reflecting [its] longstanding policy of deference to legislative judgments." *Id.* If condemning Ms. Kelo's home so that a pharmaceutical company could build a facility served the public purpose of economic development, then so would facilitating Mississippians' access to medications for which manufacturers have already agreed to provide a discount. *See Sanofi-Aventis*, 570 F. Supp. 3d at 209 ("The 340B Program assists uninsured patients in affording costly medications and under-resourced providers in

[4] *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals, 85 Fed. Reg. 48,772, 48,886–90 (Aug. 12, 2020) (explaining the methodology underlying the estimated 34.7% average 340B discount, when drugs are penny-priced, and why CMS considered penny drugs as outliers in its analysis).

serving more people, decidedly public purposes even if it is also true that contract pharmacies benefit from the Program.").

Plaintiffs seek a preliminary injunction on the theory that H.B. 728 effects a taking for private use, which would be unconstitutional and subject to injunctive relief. *See* Mem. [9] at 20–22. On the other hand, "[e]quitable relief is not available to enjoin an alleged taking of private property for a public use, duly authorized by law, when a suit for compensation can be brought against the sovereign subsequent to the taking." *Monsanto*, 467 U.S. at 1016. Plaintiffs have not moved for a preliminary injunction on a theory that H.B. 728 effects a taking for public use for which just compensation is owed. *See* Mem. [9] at 20–22. So, the Court's conclusion that H.B. 728 serves a public purpose, *see Kelo*, 545 U.S. at 480, is also a sufficient reason to deny Plaintiffs' Motion [8] as to their takings claim.

III. CONCLUSION

Because Plaintiffs have not shown a substantial likelihood of success on the merits as required to obtain a preliminary injunction, they are not entitled to such relief, and the Court need not address the remaining Rule 65 factors. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 23–24 (2008) (declining to address other preliminary injunction factors after finding against the plaintiffs on one such factor). To the extent the Court has not addressed any of the parties' remaining arguments, it has considered them and determined they would not alter the Court's conclusion.

IT IS, THEREFORE, ORDERED AND ADJUDGED THAT, Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, and Allergan Sales, LLC's Motion [8] for Preliminary Injunction is **DENIED**.

SO ORDERED AND ADJUDGED, this the 22nd day of July, 2024.

s/ Halil Suleyman Ozerden
HALIL SULEYMAN OZERDEN
UNITED STATES DISTRICT JUDGE